DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 18, 1999

Federal Y2K Special Data Request
Y2K Readiness Survey of Manufacturers of Essential Medical Supplies

Dear Medical Device Firm President/CEO:

During the past year, we have asked that biomedical equipment manufacturers provide Year 2000 (Y2K) status information regarding their products. Because of your positive response, we have been able to create a Y2K web site that has become an essential resource for biomedical equipment users regarding the Y2K status of products.

I am writing to ask for further information regarding the readiness of your firm to transition into the Year 2000 with particular emphasis on your mission critical automated manufacturing and distribution systems rather than for Y2K status information on specific products. Information is needed on the preparation and readiness of manufacturers of medical supplies to continue uninterrupted production of essential supplies This information will provide further assurance to the FDA, the healthcare community, and the public that an adequate supply of essential medical devices, including consumable and disposable devices, will be available as we move into the year 2000 The intended respondents for this survey are manufacturers of essential medical supplies which are required by healthcare facilities on a regular and continuing basis (please see the instruction sheet for clarification).

As part of your preparations for Y2K, we expect that biomedical equipment manufacturers will thoroughly review and test all computer systems, including those involved in the supply, manufacturing, and distribution of your products, and have appropriate contingency plans in place before January 1, 2000. We further expect that all procedures to achieve this goal will be appropriately tested and validated prior to implementation. And we expect that each firm will establish policies and procedures to monitor customer demand and ensure that unusual ordering or stockpiling, which could stress production capacity, does not compromise product availability to all customers.

Please complete the attached survey, which inquires about the status of actions your firm has taken to address the above issues in the production and distribution of your products. To assist you in this important effort, we have enclosed an instruction sheet that describes the type and level of information we are seeking.

This survey is a "special Year 2000 data gathering request" under Section 4(f) of the Year 2000 Information and Readiness Disclosure Act. The details of the information submitted by your firm in response to this survey will not be available to the public as described in the instructions. Please be aware, however, that Y2K readiness information related to manufacturing processes should be readily available for FDA review during possible inspections.

Because of the limited time available before the year 2000, we request that you complete and return the attached Y2K Assessment Readiness Survey **within fifteen (15) days of the receipt of this letter** to:

Food and Drug Administration
Center for Devices and Radiological Health, HFZ-Y2K
Y2K Coordinator
9200 Corporate Boulevard
Rockville, Maryland 20850

Fax: 301-881-1848

If you have received this request and do not manufacture essential medical supplies, please respond with a statement that you do not currently manufacture essential supplies so that we may record a response from your firm.

I know that you share our commitment to the uninterrupted availability of needed medical supplies and, therefore, I look forward to your prompt response to this request for information

Sincerely yours,

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration

Enclosures: Y2K Assessment Readiness Survey
Instruction Sheet